

In the Claims

Please replace all prior versions, and listings, of claims in the application with the following list of claims:

1. (Currently Amended) A method for inducing a mucosal immune response, comprising: administering to a subject in need of a mucosal immune response an effective amount for inducing a mucosal immune response of an oligonucleotide 8 to 100 nucleotides in length, having a sequence including at least the following formula:

5' X₁ X₂CGX₃ X₄ 3'

wherein C is unmethylated, wherein X₁, X₂, X₃, and X₄ are nucleotides, and an antigen,
wherein the antigen is not encoded in a nucleic acid vector, the oligonucleotide and the antigen are both administered to the same mucosal surface of the subject vaginally, rectally, intranasally, ocularly, or by inhalation to the subject, a cytokine and an immune stimulating complex (ISCOM™) are not administered to the subject, and the antigen is not a *Streptococcus pneumoniae* antigen.

2.-3. (Cancelled)

4. (Previously Presented) The method of claim 1, wherein the antigen is administered concurrently with the oligonucleotide.

5. (Previously Presented) The method of claim 1, wherein the antigen is delivered in conjunction with a colloidal dispersion system.

6. (Original) The method of claim 5, wherein the colloidal dispersion system is selected from the group consisting of macromolecular complexes, nanocapsules, microspheres, beads, and lipid-based systems.

7. (Original) The method of claim 6, wherein the lipid-based system is selected from the group consisting of oil-in-water emulsions, micelles, mixed micelles, and liposomes.

8. (Previously Presented) The method of claim 1, further comprising the step of administering a non-oligonucleotide mucosal adjuvant in conjunction with the antigen.

9. (Currently Amended) The method of claim 8, wherein the non-oligonucleotide mucosal adjuvant is selected from the group consisting of cholera toxin, derivatives of cholera toxin, heat-labile enterotoxin, derivatives of ~~cholera toxin or~~ heat-labile enterotoxin, alum, monophosphoryl lipid A (MLP), muramyl dipeptide (MDP), saponins, such as QS21, cytokines, oil-in-water and other emulsion formulations, such as squalene-in-water emulsion stabilized with Span 85 and Tween 80 (MF59), syntext adjuvant formulation (SAF), Montanide ISA 720 and oil-in-water emulsion containing stabilizing detergent and micelle-forming agent (PROVAX®), and poly[di(carboxylatophenoxy)phosphazene (PCPP) polymers, and ISCOMS.

10.-11. (Cancelled)

12. (Previously Presented) The method of claim 1, wherein the subject is a subject at risk of developing an infectious disease.

13. (Previously Presented) The method of claim 1, wherein the subject is at risk of developing cancer.

14. (Cancelled)

15. (Original) The method of claim 1, wherein the oligonucleotide includes a phosphate backbone modification which is a phosphorothioate or phosphorodithioate modification.

16. (Original) The method of claim 15, wherein the phosphate backbone modification occurs at the 5' end of the oligonucleotide.

17. (Original) The method of claim 15, wherein the phosphate backbone modification occurs at the 3' end of the oligonucleotide.

18. (Original) The method of claim 1, wherein X₁X₂ are nucleotides selected from the group consisting of: GpT, GpG, GpA, ApA, ApT, ApG, CpT, CpA, CpG, TpA, TpT, and TpG; and X₃X₄ are nucleotides selected from the group consisting of: TpT, CpT, ApT, TpG, ApG, CpG, TpC, ApC, CpC, TpA, ApA, and CpA.

19. (Original) The method of claim 1, wherein the oligonucleotide has a sequence including at least the following formula:

5' TCNTX₁X₂CGX₃X₄ 3'

wherein X₁, X₂, X₃, and X₄ are nucleotides, N is a nucleic acid sequence composed of from about 0-25 nucleotides.

20. (Currently Amended) The method of claim 1, wherein the antigen is selected from the group consisting of cells, cell extracts, proteins, polypeptides, peptides, polysaccharides, polysaccharide conjugates, peptide mimics of polysaccharides, lipids, glycolipids, carbohydrates, allergens, viruses and viral extracts and parasites.

21. (Cancelled)

22. (Currently Amended) The method of claim 1, wherein the antigen is derived obtained from an infectious organism selected from the group consisting of infectious bacteria, infectious viruses, infectious parasites, and infectious fungi.

23.-24. (Cancelled)

25. (Previously Presented) The method of claim 1, further comprising administering a B-7 costimulatory molecule.

26. (Currently Amended) The method of claim 1, wherein the mucosal immunity immune response is induced in a remote site.

27. (Original) The method of claim 1, further comprising administering a boost of the oligonucleotide.

28. (Original) The method of claim 8, further comprising administering a boost of the oligonucleotide and the non-oligonucleotide mucosal adjuvant.

29-128. (Cancelled)

129. (Previously Presented) The method of claim 1, further comprising identifying a subject in need of a mucosal immune response.

130.-134. (Cancelled)

135. (Previously Presented) The method of claim 1, wherein the antigen is a viral antigen.

136. (Currently Amended) A method for inducing a mucosal immune response, comprising: administering to a subject in need of a mucosal immune response an effective amount for inducing a mucosal immune response of an oligonucleotide 8 to 100 nucleotides in length, having a sequence including at least the following formula:

5' X₁ X₂CGX₃ X₄ 3'

wherein C is unmethylated, wherein X₁, X₂, X₃, and X₄ are nucleotides,

a non-oligonucleotide mucosal adjuvant that is not an immune stimulating complex (ISCOMTM), and

an antigen,

wherein the antigen is not encoded in a nucleic acid vector, and wherein the oligonucleotide and the non-oligonucleotide mucosal adjuvant are administered ~~to a mucosal surface of intranasally, rectally, intravaginally, ocularly, or by inhalation to the subject, and a cytokine is not administered to the subject.~~

137. (New) A method for inducing a mucosal immune response, comprising:

administering to a subject in need of a mucosal immune response an effective amount for inducing a mucosal immune response of an oligonucleotide 8 to 100 nucleotides in length, having a sequence including at least the following formula:

5' X₁ X₂CGX₃ X₄ 3'

wherein C is unmethylated, wherein X₁, X₂, X₃, and X₄ are nucleotides, and

a viral antigen,

wherein the antigen is not encoded in a nucleic acid vector, the oligonucleotide and the antigen are both administered vaginally, rectally, intranasally, ocularly, or by inhalation to the subject, and a cytokine and an immune stimulating complex (ISCOMTM) are not administered to the subject.

138. (New) A method for inducing a mucosal immune response, comprising:

administering to a subject in need of a mucosal immune response an effective amount for inducing a mucosal immune response of an oligonucleotide 8 to 100 nucleotides in length, having a sequence including at least the following formula:

5' X₁ X₂CGX₃ X₄ 3'

wherein C is unmethylated, wherein X₁, X₂, X₃, and X₄ are nucleotides, and

exposing the subject to an antigen,

wherein the antigen is not encoded in a nucleic acid vector, oligonucleotide administration and antigen exposure both occur vaginally, rectally, intranasally, or by inhalation, and a cytokine and an immune stimulating complex (ISCOMTM) are not administered to the subject.

139. (New) A method for inducing a mucosal immune response, comprising:

administering to a subject in need of a mucosal immune response an effective amount for inducing a mucosal immune response of an oligonucleotide 8 to 100 nucleotides in length, having a sequence including at least the following formula:

5' X₁ X₂CGX₃ X₄ 3'

wherein C is unmethylated, wherein X₁, X₂, X₃, and X₄ are nucleotides, and

an antigen,

wherein the antigen is not encoded in a nucleic acid vector, the oligonucleotide and the antigen are both administered vaginally, rectally, or ocularly to the subject, and a cytokine and an immune stimulating complex (ISCOM™) are not administered to the subject.

140. (New) The method of claim 139, wherein the antigen is a viral antigen.

141. (New) A method for inducing a mucosal immune response, comprising:

administering to a subject in need of a mucosal immune response an effective amount for inducing a mucosal immune response of an oligonucleotide 8 to 100 nucleotides in length, having a sequence including at least the following formula:



wherein C is unmethylated, wherein X₁, X₂, X₃, and X₄ are nucleotides, and an antigen,

wherein the antigen is not encoded in a nucleic acid vector and is not a *Streptococcus pneumoniae* antigen, the oligonucleotide and the antigen are both administered intranasally or by inhalation to the subject, and a cytokine and an immune stimulating complex (ISCOM™) are not administered to the subject.

142. (New) The method of claim 136, wherein the antigen is selected from the group consisting of cells, cell extracts, proteins, polypeptides, peptides, polysaccharides, polysaccharide conjugates, peptide mimics of polysaccharides, lipids, glycolipids, carbohydrates, viruses and viral extracts and parasites.

143. (New) The method of claim 137, wherein the antigen is selected from the group consisting of cells, cell extracts, proteins, polypeptides, peptides, polysaccharides, polysaccharide conjugates, peptide mimics of polysaccharides, lipids, glycolipids, carbohydrates, viruses and viral extracts and parasites.

144. (New) The method of claim 138, wherein the antigen is selected from the group consisting of cells, cell extracts, proteins, polypeptides, peptides, polysaccharides, polysaccharide

conjugates, peptide mimics of polysaccharides, lipids, glycolipids, carbohydrates, viruses and viral extracts and parasites.

145. (New) The method of claim 139, wherein the antigen is selected from the group consisting of cells, cell extracts, proteins, polypeptides, peptides, polysaccharides, polysaccharide conjugates, peptide mimics of polysaccharides, lipids, glycolipids, carbohydrates, viruses and viral extracts and parasites.

146. (New) The method of claim 141, wherein the antigen is selected from the group consisting of cells, cell extracts, proteins, polypeptides, peptides, polysaccharides, polysaccharide conjugates, peptide mimics of polysaccharides, lipids, glycolipids, carbohydrates, viruses and viral extracts and parasites.